

STATE OF MAINE
RULES RELATING TO BOTTLED WATER, BULK WATER, AND
WATER VENDING MACHINES

10-144

DEPARTMENT OF HUMAN SERVICES
DIVISION OF HEALTH ENGINEERING
10 STATE HOUSE STATION
AUGUSTA, MAINE 04333

Chapter 235

EFFECTIVE DATE

These rules are effective May 7, 2001

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Chapter 235

Department of Human Services
Bureau of Health
Drinking Water Program

STATE OF MAINE

RULES RELATING TO BOTTLED WATER, BULK WATER AND WATER VENDING
MACHINES

SUMMARY STATEMENT

These Rules are established to ensure all water bottled or distributed in the State of Maine is free from any contaminants known to be harmful to public health and safe for consumption by the general public.

AUTHORITY

These rules are promulgated under the authority of 22 M.R.S.A. §§42 and 2601 *et seq.*

Non-Discrimination Notice

In accordance with Title VI of the Civil Rights Act of 1964, as amended by The Civil Rights Restoration Act of 1991 (42 U.S.C. 1981, 2000e *et seq.*) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), The Age Discrimination Act of 1975, as amended (42 U.S.C. 6101 *et seq.*), Title II of the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*), and Title IX of the Education Amendments of 1972, the Maine Department of Human Services does not discriminate on the basis of sex, color, national origin, disability or age in admission or access to or treatment or employment in its programs and activities.

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1. GENERAL PROVISIONS

- A. **APPLICATION AND SCOPE.** These rules shall apply to all producers and processors of bottled and bulk drinking water. The Rules establish the sanitary requirements for the installation and maintenance of equipment used in bottling, processing, handling, and storage and the source of water.
- B. **CONSTITUTIONALITY CLAUSE.** Should any section, paragraph, sentence, clause, or phrase of these regulations be declared unconstitutional or invalid for any reason, the remainder of said regulations shall not be affected thereby.
- C. **EXCEPTION.** These rules shall not apply to any public water systems that bottle water for educational, promotional or any other purpose free of charge from an approved water source, so long as the bottled water supply is in compliance with the State of Maine Rules Relating to Drinking Water, Rules Relating to Bottled Water, U.S. Food and Drug Administration (FDA) and Good Manufacturing Practices (GMPs). Failing to comply with the Maine Rules Relating to Drinking Water, Rules Relating to Bottled Water, U.S. Food and Drug Administration (FDA) and Good Manufacturing Practices (GMPs) creates a threat to public health, which would result in a loss of exception status. In order to fall under this exception, the Water System must comply with the following:
 - 1. Bottling equipment, bottling procedures and bacteriological analysis would be subject to an annual inspection by the Department.
 - 2. The Water System will notify the Department of any contamination detected in the bottling procedure.

2. DEFINITIONS

ADULTERATED: A bottled water containing a substance at a level considered potentially injurious to health, regardless of whether or not the bottled water bears a label statement of substandard quality.

APPROVED SOURCE: When used in reference to a bottled water plant's product water or water used in the plant's operations, means the source of the water whether it be from a spring, artesian well, drilled well, public or community water system, or any other source that has been inspected and the water sampled, analyzed, and found of a safe and sanitary quality with or without treatment. Approval shall be obtained and maintained in accordance with Section 4 of these Rules. The bottler shall maintain in the plant a letter of approval from the Department which shall constitute approval of the source and which shall be available for inspection by the Department, and a copy of which shall be made available to consumers upon request.

ARTESIAN WATER: A well tapping a confined aquifer in which the water level stands at some height above the top of the aquifer. Artesian water may be collected with the assistance of external force to enhance the natural underground pressure. On request, plants shall demonstrate to appropriate regulatory officials that the water level stands at some height above the top of the aquifer.

BOTTLED WATER: Water that is intended for human consumption and is placed in bottles, packages or other containers and offered for sale or freely distributed to the public; whether or not the container is provided ~~for~~ by the water supplier ~~or not~~.

BOTTLING: The act or operation of filling bottles or other containers with water intended for human consumption.

BOTTLING ROOM: The room or plant area in which the actual bottling of water is done.

BULK WATER: Water intended for potable uses which is transported across municipal boundaries, in containers greater than 10 gallons for the purpose of treatment, packaging or human consumption.

CERTIFIED LABORATORY: A laboratory (1) approved by the State of Maine Drinking Water Program (Department) pursuant to 22 M.R.S.A. § 567; (2) certified by the U.S. Environmental Protection Agency (EPA) pursuant to 40 CFR Section 141.28; (3) certified by the primary enforcement authority in any state which has been granted primacy by EPA; (4) or certified (accredited) by a third-party organization acceptable to a primacy or EPA.

CONTAINERS: Containers are bottles or any other article pre-packaged in which water intended for human consumption is placed for sale.

CONTAMINANT: Any physical, chemical, biological, or radiological substance or matter in water.

DEIONIZED WATER: Water produced by a process of de-ionization and that meets the definition of "purified water" in the United States Pharmacopoeia.

DEMINERALIZED WATER: Bottled water produced by distillation, de-ionization, reverse osmosis, or other suitable process and that meets the definition of purified water in the United States Pharmacopoeia.

DEPARTMENT: The State of Maine Department of Human Services, Bureau of Health, Division of Health Engineering, Drinking Water Program, or its authorized representative.

DISINFECTION: The application of an effective method for the destruction of pathogens and other microorganisms. Such treatment shall not adversely affect the equipment, the water, or the health of consumers, nor shall it leave a residual.

DISTILLED WATER: Water produced by a process of distillation and meets the definition of "purified water" in the United States Pharmacopoeia.

GROUND WATER: Water from a subsurface saturated zone that is under a pressure equal to or greater than atmospheric pressure. Ground water must not be under the direct influence of surface water.

HEALTH and ENVIRONMENTAL TESTING LABORATORY (HETL): The Department of Human Services certified public Health and Environmental Testing Laboratory.

IMMINENT HEALTH HAZARD: Includes, without limitation:

1. An extended loss of water supply.
2. An extended power outage.
3. A sewer backup into the plant.
4. Any other violation that has the potential to pose an imminent threat to public health, as determined by the Department. Failure to include other violations in this definition shall not be construed as a determination that other violations may not, in light of the circumstances, be found to pose an imminent health hazard.

LOT: A collection of primary containers or unit packages of the same size, type, and style produced under conditions as nearly uniform as possible and designated by a common container code or marking.

MAXIMUM CONTAMINANT LEVEL (MCL): The highest level of a contaminant in bottled water below, which there is no known or expected health risk.

MINERAL WATER: Bottled drinking water containing not less than 250 milligrams per liter of total dissolved solids, coming from a source tapped at one or more bore holes or springs, originating from a geologically and physically protected underground water source. Mineral water shall be distinguished from other types of water by its constant level and relative proportions of minerals and trace elements at the point of emergence from the source, due account being taken of the cycles of natural fluctuations. No minerals may be added to this water.

MISLABEL: To incorrectly or falsely indicate (or omit) on the label of bottled water, the presence of a substance or chemical, which is at or above the applicable detection limit.

MULTI-USE CONTAINERS: Those containers, which are intended by the bottler for more than one use. These items shall be capable of being sanitized.

NATURAL WATER: Bottled spring, mineral, artesian, or well water which is derived from an underground formation or water from surface water that only requires minimal processing, is not derived from a municipal system or public water supply, and is unmodified except for limited treatment (e.g., filtration, ozonation, UV or equivalent disinfection process).

NONTOXIC MATERIALS: Materials, which are free of substances which may render the water injurious to health or which may adversely affect the flavor, color, odor, or bacteriological quality of the product.

NATIONAL SANITATION FOUNDATION (NSF): Is an independent, not-for-profit organization, which has been committed to public health safety and protection of the environment by developing standards, by providing education and by providing third-party conformity assessment services while representing the interest of all stakeholders. NSF is widely recognized for its scientific and technical expertise in health and environmental sciences.

OPERATIONS WATER: Water that is delivered under pressure from a source approved for drinking water by the Department and used in a plant for bottle washing, hand washing, plant cleanup, and other sanitary purposes.

OZONATION: Water that is disinfected by a process utilizing ozone and that meets the definition of "purified water" in the United States Pharmacopoeia, 23d Revision, January 1, 1995.

PLANT: An establishment in which bottled water or bottled carbonated nonalcoholic beverages are prepared for shipment and/or sale.

PRODUCT: Water or carbonated nonalcoholic beverages that is intended to be placed in containers for shipment and/or sale or bottled water or bottled carbonated nonalcoholic beverages.

PUBLIC WATER SYSTEM: Any water system meeting the definition found in Section 2 of the State of Maine Rules Relating to Drinking Water 10-144 CMR 231.

PURIFIED WATER: Bottled water produced by distillation, de-ionization, reverse osmosis, or other suitable process and that meets the definition of purified water in the most recent edition of the United States Pharmacopoeia.

RAW SOURCE WATER: Water taken directly from the borehole, spring, drilled well, or dug well prior to disinfection, filtration, or other treatment processes.

REVERSE OSMOSIS: Water that is produced by a process of reverse osmosis and that meets the definition of "purified water" in the United States Pharmacopoeia.

SANITARY SURVEY: An on-site inspection of the water source, facilities, equipment, operation and maintenance of a public water system for the purpose of evaluating the protection of the source; and evaluating the adequacy of such source, facilities, equipment, operation and maintenance for producing and distributing safe drinking water.

SANITIZATION: Means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

SINGLE-SERVICE CONTAINERS: Those containers, which are intended by the bottler for one usage only and which normally would not be washed and sanitized prior to use.

SPRING WATER: Water derived from an underground formation from which water flows naturally to the surface of the earth. Spring water must comply with the U.S. EPA National Primary and Secondary Drinking Water Standards, 40 CFR Section 141, from time to time amended. Spring water shall be collected only at the spring or through a borehole tapping the underground formation feeding the spring. There shall be a natural force causing the water to flow to the surface through a natural orifice. The location of the spring shall be identified and such identification shall be maintained in the plant's records. Spring water collected with the use of an external force shall be from the same underground stratum as the spring, as shown by a measurable hydraulic connection using a hydro geologically valid method between the bore hole and the natural spring, and shall have all the physical properties, before treatment, and be of the same composition and quality, as the water that flows naturally to the surface of the earth. A water chemistry comparison is typically done by plotting cations and anions for both the spring and borehole on a "Piper Diagram". If spring water is collected with the use of an external force, water must continue to flow naturally to the surface of the earth through the spring's natural orifice. Plants shall demonstrate, on request, to appropriate regulatory officials, using a hydro geologically valid method that an appropriate hydraulic connection exists between the natural orifice of the spring and the borehole. Such a demonstration shall be submitted by a hydro geologist certified to perform this type of work in the State of Maine.

STANDARD OF QUALITY: The bottled water that meets the National Primary and Secondary Drinking Water Standards, attached as Appendix A.

SURFACE WATER: All water naturally open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors which are directly influenced by surface water.

UV DISINFECTION: Water that is disinfected by a process utilizing ultra violet radiation and that meets the definition of "purified water" in the United States Pharmacopoeia, 23d Revision, January 1, 1995.

WATER DEALER: Any person who oversees the delivery of water, imports bottled water, or causes bulk water to be transported for bottling for human consumption or other consumer uses.

WELL WATER: Water from a hole bored, drilled, or otherwise constructed in the ground, which taps the water of an aquifer.

WATER VENDING MACHINES: Any self-service device which upon insertion of coins or tokens and dispenses unit servings of water into a customer's container. Stationary or mobile water tank trucks with serving spigots are included in this definition.

3. LICENSING

A. **GENERAL REQUIREMENTS.** No person shall operate a bottled water plant, or bottle water for the purpose of sale or distribution, in the State of Maine without first obtaining a license demonstrating that the bottling facility, treatment and bottling practices, product labels, raw source and finished product water quality meet the requirements of these rules and the requirements of state and federal law. Licensing consists of an application review process, by providing the Department with the following documentation:

1. **APPLICATION.** A completed "Request to Sell Bottled Water in Maine" application.
2. **WATER QUALITY ANALYSIS.** A minimum 48-hour pump test shall be done for each production well, prior to water quality analysis sampling. Untreated (raw) source water and finished product water shall be analyzed to characterize the water's microbiological, chemical, physical, and radiological characteristics:
 - (a) **Microbiological Quality.** A test for total coliforms, fecal coliforms and E. Coli. No sample shall have a coliform bacteria or E. Coli positive result (one or more colony forming units per 100 milliliters of sample tested).

- (b) Total Nitrogen. A test for nitrate and nitrite nitrogen. No samples shall exceed the MCL for each of these contaminants, according to the U.S. EPA's National Primary Drinking Water Regulations, 40 CFR Section 141, as from time to time amended, or in accordance with the State of Maine Rules Relating to Drinking Water, 10-144 CMR 231, as from time to time amended, whichever are more stringent.
- (c) Inorganics Screen. A test for chloride, hardness, fluoride, copper, iron, manganese, zinc, arsenic, barium, cadmium, chromium, lead, mercury, silver, selenium, sodium, color, turbidity and pH. No samples shall exceed the MCL for each of these contaminants, according to the U.S. EPA's National Primary Drinking Water Regulations, 40 CFR Section 141, as from time to time amended, or in accordance with the State of Maine Rules Relating to Drinking Water, 10-144 CMR 231, as from time to time amended, whichever are more stringent.
- (d) Semivolatile Organics Screen. A test for most synthetically produced chemicals. No samples shall exceed the MCL for each of these contaminants, according to the U.S. EPA's National Primary Drinking Water Regulations, 40 CFR Section 141, as from time to time amended, or in accordance with the State of Maine Rules Relating to Drinking Water, 10-144 CMR 231, as from time to time amended, whichever are more stringent.
- (e) Volatile Organics Screen. A test for most common solvents, degreasers and many low boiling organic industrial pollutants. No samples shall exceed the MCL for each of these contaminants, according to the U.S. EPA's National Primary Drinking Water Regulations, 40 CFR Section 141, as from time to time amended, or in accordance with the State of Maine Rules Relating to Drinking Water, 10-144 CMR 231, as from time to time amended, whichever are more stringent.
- (f) Radiological Screen. Tests for Gross Alpha, Radium, Uranium and Radon, respectively. No samples shall exceed the MCL for each of these contaminants, according to the U.S. EPA's National Primary Drinking Water Regulations, 40 CFR Section 141, as from time to time amended, or in accordance with the State of Maine Rules Relating to Drinking Water, 10-144 CMR 231, as from time to time amended, whichever are more stringent.
- (g) Miscellaneous. Any other tests that the Department deems necessary due to surrounding environmental conditions, or other

circumstances. Such monitoring shall be done at regular intervals, as determined by the Department, with testing/monitoring results submitted to the Department within timeframes established by the Department.

3. **HYDROGEOLOGIC REPORT.** A report on the regional geology surrounding the site and the specific site geology. A description of the vertical and horizontal extent of the source aquifer using existing data. The information will be used to define the recharge area of the aquifer, or in the case of regional aquifers, the zone of influence of the subject source. A report detailing the development of the source; the method of construction including spring design, well installation, surface catchment, and intake structures; and transmission facilities as appropriate. A watershed survey of the recharge area or zone of influence of subject source that identifies and evaluates actual and potential sources of contamination. A minimum 48-hour pump test shall be conducted on each well to determine safe yield. Based on the findings in the hydro geologic report, a plan for special monitoring of any significant contaminant source and for taking restrictive preventive or corrective measures as appropriate to protect the source water. Such a report shall be completed, certified and submitted by a hydro geologist certified to perform this type of work in the State of Maine.
4. **PLANT INSPECTION:**
 - (a) Within the State of Maine. An inspection of the site and facilities by an authorized staff member of the Department prior to the sale of any water. Inspection parameters shall be in accordance with Section 9 of these Rules.
 - (b) Outside the State of Maine. Documentation that the plant has satisfactorily passed a sanitary survey inspection by the department or government agency with jurisdiction. The plant inspection shall certify that said source, facility, treatment, bottling practices, and product water meet the standards of the country of origin, except those that are in conflict with U.S. State and Federal laws and regulations.
5. **BOTTLE LABELS.** At least one label for each product, in accordance with Section 8 of these Rules.

- B. **MAINE DEPARTMENT OF AGRICULTURE, FOOD & RURAL RESOURCES.** Pursuant to 32 MRSA Section 1851: license required, fee, expiration and renewal.

No person within this State may manufacture or bottle for sale any beverage without first having filed with the Commissioner of Agriculture, Food and Rural Resources an application for a license accompanied with the fee specified in this section and having been issued a license to operate a beverage plant. Upon receipt of such application containing information required by the Commissioner and being satisfied that the applicant has complied with this chapter and rules adopted under this chapter, the Commissioner shall issue the applicant a license to manufacture and sell beverages.

No person manufacturing or bottling any beverage outside of the State for retail sale within the State may sell or offer to sell the same within the State unless that person has made application and secured a license to sell beverages from the Commissioner upon the payment of the fee specified in this section. The Commissioner may issue a license to sell beverages manufactured or bottled outside of the State upon being satisfied from inspection by an inspector of the Department or from a statement from the agency having enforcement of the beverage law in the State where the beverage establishment is located, that the establishment complies with the requirements of this chapter and rules adopted under this chapter, and upon the Commissioner's approval of establishment on the basis of the inspection or statement.

Beginning August 1, 2000, each license or license renewal issued expires on the 31st day of December following the date of issuance or on the date provided by the provisions of the Maine Administrative Procedure Act as to license expiration, whichever date is later, unless sooner revoked as provided in section 1802, and must be renewed annually thereafter subject always to such revocation. When an initial license is issued or when a license is renewed between August 1, 2000 and December 31, 2001, the license fee is prorated based on the number of months the license is valid and the annual license fee.

The fee for a license issued under this section is based on the number of persons employed by the manufacturer or bottler. The fee for a manufacturer or bottler with 5 or fewer employees is \$50. The fee for all other manufacturers or bottlers is \$100.

4. SOURCES OF WATER

- A. **APPROVAL REQUIRED.** As part of licensure, the source water (i.e. spring, bore hole, well, etc.) of all bottled or bulk water offered or exposed for sale or distribution within the State of Maine, or meeting the definition of a public water system, must receive prior approval from the Department.
- B. **GENERAL SOURCE REQUIREMENTS.** All sources must meet the water quality requirements of Section 3.C of these Rules.

1. IN-STATE SOURCES:

- (a) All new water sources or substantial modifications to a water source or treatment to bring a source water into compliance with the State of Maine Rules Relating to Drinking Water 10-144 CMR 231, or substantial modifications to said treatment shall be approved by the Department in accordance with current laws, regulations and guidelines established by the Department, prior to using or modifying the water source or treating the source water.
- (b) All water sources shall be located, developed, and protected so they are not subject to natural or artificial contamination. If necessary, source water can be treated in order to control natural or artificial contamination. All source water must not exceed the MCL for any of the water quality parameters listed in Section 3.C of these Rules.

2. OUT OF STATE AND FOREIGN SOURCES:

- (a) Out-of-state and foreign water sources shall be approved by the governmental agency having jurisdiction.
- (b) All source water must not exceed the MCL for any of the water quality parameters listed in Section 3.C of these Rules.

C. PHYSICAL REQUIREMENTS.

1. SPRINGS. All new spring construction and/or modifications to existing springs shall meet the following minimum requirements:

- (a) There shall be a watertight wall completely surrounding the spring not less than 18 inches above the highest point of the ground and extending down through the overburden to water-bearing stratum. The top of the surrounding wall shall be constructed in such a manner as to accommodate a cover.
- (b) A tight fitting, locked cover shall be installed on top of the encircling wall to protect against contamination or vandalism.
- (c) Where the spring is protected by a springhouse, the building shall be rodent and insect proof and shall be kept locked.

- (d) A ditch, or ditches shall be dug to divert surface waters away from the spring. These ditches must be maintained free of debris that would interfere with proper diversion of surface water.
 - (e) Springs meeting the definition of a surface water shall comply with the regulations pursuant to Section 7(H) of the State of Maine Rules Relating to Drinking Water 10-144 CMR 231 and 40 CFR Section 141.70 of the U.S. EPA's National Primary Drinking Water Regulations, as from time to time amended.
- 2. **DRILLED WELLS.** Drilled wells shall be properly located with reference to surrounding sanitary conditions, properly developed, and protected against contamination. Drilled wells shall meet the minimum following requirements:
 - (a) The drilled well shall be sealed watertight to the depth necessary to prevent surface contamination, and to seal off contamination of undesirable strata.
 - (b) The top of the well casing shall be at least 18 inches above ground level unless otherwise protected.
 - (c) A sanitary seal shall be installed at the joint where the discharge pipe passes through the well casing.
 - (d) Dug wells meeting the definition of a surface water shall comply with the regulations pursuant to Section 7(H) of the State of Maine Rules Relating to Drinking Water 10-144 CMR 231 and 40 CFR Section 141.70 of the U.S. EPA's National Primary Drinking Water Regulations, as from time to time amended.
- 3. **DUG WELLS OR DRIVEN WELL POINTS.** Dug wells or driven well points in shallow aquifers are not recommended as sources of water supply. If these are in use, then they shall meet the minimum following requirements:
 - (a) They must be properly constructed according to good sanitary engineering practices and protected against potential contamination.
 - (b) Dug wells and driven well points shall have a watertight lining extending at least six (6) feet below the ground surface. Dug wells must be back filled with clay from the ground surface to a depth of not less than four (4) feet.

5. WATER QUALITY MONITORING/REPORTING

- A. **GENERAL REQUIREMENTS.** All plants producing carbonated nonalcoholic beverages whose water source is not a public water supply and all plants producing bottled water shall be responsible for sampling and testing for all physical, chemical, microbiological and radiological parameters as previously specified in Section 3.C of these Rules.

1. RAW SOURCE WATER.

- (a) Analyses shall be conducted by a certified laboratory in accordance with the testing and methodological requirements specified by the U.S. EPA's National Primary Drinking Water Regulations, 40 CFR Section 141, as from time to time amended.
- (b) Samples of raw source water are to be taken by the plant and analyzed by a certified laboratory as often as necessary, but at a minimum frequency of once each year, for chemical, physical, and radiological contaminants. Additionally, source water obtained from any source other than a public water system is to be sampled and analyzed for microbiological contaminants at least once each week. The Department requires submission of one representative quarterly microbiological analytical test result from each source.

2. FINISHED PRODUCT.

- (a) Analyses shall be conducted by a certified laboratory in accordance with the sampling, testing and methodological requirements specified by the U.S. EPA's National Primary Drinking Water Regulations, 40 CFR Section 141, as from time to time amended.
- (b) Samples of each type of bottled product produced are to be taken by the plant and analyzed by a certified laboratory as often as necessary, but at a minimum frequency of once each year for chemical, physical, and radiological contaminants. The Department requires submission of one representative quarterly microbiological test from each product, analyzed by a certified laboratory. The representative sample shall consist of primary containers of product or unit packages of product.
- (c) On-site bacteriological analysis shall be taken for each production run, on a weekly basis (at a minimum). A certified laboratory analysis is not required for weekly sampling, however all standard

laboratory procedures shall be followed in accordance with U.S. EPA guidelines.

- B. **ADDITIONAL TESTING.** Notwithstanding any other provisions of 10-144 CMR 231 and these rules, the Department may require any bottler, distributor or vendor of bottled water or carbonated nonalcoholic beverages or any applicant for a permit, to test and submit results to the Department for any substance at any time when the Department has reason to believe that the substance may be present in a water source and may threaten public health. Likewise, the Department reserves the right to increase testing/monitoring frequency based upon the potential health risk.
- C. **SUBMISSION OF TEST RESULTS.** Copies of the water quality testing results as required in Section 5.A.1 and 5.A.2, shall be submitted to the Department no later than one week after the compliance period ends. All test results submitted to the Department shall be an official copy signed by the applicable laboratory manager of the certified laboratory performing the analysis.
- D. **WATER VENDING MACHINES.** Pursuant to 22 M.R.S.A. § 2613 (3), A bacteriological sample of the water vending machine must be submitted to the Department at least every 3 months. If the water vending machine has a one-year history of no coliform bacteria contamination, the Department may reduce the frequency of sampling to one sample per year. [1991, c. 113 (new).]
- E. **RECORD KEEPING.** Records of required sampling and testing shall be maintained in a separate file at the plant and shall be made available to the inspectors of the Department and/or local health official during an inspection.

6. WATER QUALITY STANDARDS

- A. **RAW SOURCE WATER.** Raw (untreated) source water shall not exceed the MCLs as specified in the U.S. EPA's National Primary Drinking Water Regulations, 40 CFR Section 141, from time to time amended, or in the case of source water from a Maine location, specified in the State of Maine Rules Relating to Drinking Water, 10-144 CMR 231, or in the case of source water from a location outside the United States, specified by the regulatory authorities having jurisdiction. Source water may be treated to meet these requirements, if necessary.
- B. **FINISHED PRODUCT.** Finished product bottled water sold in Maine shall not exceed the MCLs specified in the U.S. EPA National Primary Drinking Water Regulations, 40 CFR Section 141. Whenever an MCL exceedance is suspected, formal recall procedures shall commence immediately in accordance with Section 7 of these Rules.

- C. **CONTAMINATION SUSPECTED.** Whenever a bottling plant receives any test result indicating that its source water, after any customary treatment, is not in compliance with the applicable water quality standards referred to in the U.S. EPA's National Primary Drinking Water Regulations, 40 CFR Section 141, it shall immediately contact the Department. Should the contamination pose an imminent health hazard to the public, the bottler shall immediately cease bottling operations and commence product recall procedures, in accordance with Section 7 of these Rules.
- D. **AESTHETIC QUALITY.** Bottled water, the quality of which is below that prescribed by any U.S. EPA standard of quality (i.e. substandard products), shall not be sold in Maine. Aesthetic water quality problems must be reported to the Department as soon as possible.

7. **PRODUCT RECALL PROCEDURE**

- A. **GENERAL REQUIREMENTS.** Each bottled water plant operator shall develop and maintain written procedures for the notification of the Department, consumer notification, and product recall, and shall implement any said procedure as necessary with respect to any product for which the operator or Department knows or has reason to believe circumstances exist that may adversely affect its safety for the consumer. In order to facilitate product identification or recall, each bottled water product shall contain a code that is designed to remain affixed to the container during use and which contains either the date of manufacture, or a lot number.
- B. **DEPARTMENT NOTIFICATION.** A bottled water supplier who knows that the standard of quality has been exceeded or has reason to believe that circumstances exist which may adversely affect the safety of bottled water, including but not limited to source contamination, spills, accidents, natural disasters, or breakdowns in treatment, shall notify the Department immediately.
- C. **CONSUMER NOTIFICATION.** If the Department determines, based upon representative samples, risk analysis, information provided by the bottled water supplier, and other information available to the Department, that the circumstances present an imminent hazard to the public health and that a form of consumer notice or product recall can effectively avoid or significantly minimize the threat to public health, the Department may order the water supplier to initiate a level of product recall approved by the Department or, if appropriate, issue a form of notification to customers. The bottled water supplier shall be responsible for disseminating the notice in a manner designed to inform customers who may be affected by the problem. The water bottler shall, where appropriate, provide the notice to radio and television media or to the newspaper serving the affected public, or shall in the alternative directly notify affected users where doing so in a

manner approved by the Department can effectively avoid or minimize the risk to public health. Product recalls shall conform to the procedures and policies of U.S. FDA 21 CFR Section 7.

8. LABEL REQUIREMENTS

A. GENERAL REQUIREMENTS. All bottled water sold or offered for distribution in the state of Maine shall be labeled to comply with all applicable provisions under U.S. FDA 21 CFR Sections 101.1, 101.5, and 165.110(a).

B. WATER SOURCE.

1. SPRING. Water coming from springs, according to the definition in Section 2 of these rules, may be labeled “Spring Water” or “Natural Spring Water”.
2. ARTESIAN. Water meeting the definition of artesian well in Section 2, or pumped water taken from the ground, from drilled wells may be labeled “Well Water”, “Artesian Water” or “Natural Water”.
3. MUNICIPAL. When bottled water comes from a community water system, as defined in Section 2, and is labeled as such, the label shall state "from a community water system" or, alternatively, "from a municipal source" as appropriate, on the principal display panel or panels. Such labeling shall in no case be less than one-sixteenth of an inch.

C. NAME OF BOTTLER OR DISTRIBUTOR.

1. The label of a bottled product in packaged form shall specify conspicuously the name and place of business of the bottler or distributor.
2. The statement of the place of business shall include the street address, city, state and ZIP code; however, the street address may be omitted if it is shown in a current city directory or telephone directory.
3. Where the bottled product is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such bottled product; such as “Bottled for ____”, “Distributed by ____”, or any other wording that expresses the facts.
4. Such labeling shall in no case be less than one-sixteenth of an inch.

D. ADULTERATION.

1. When the microbiological, physical, chemical or radiological quality of bottled water is above that prescribed in U.S. FDA 21 CFR Section 165.110(b), from time to time amended. The label of the product shall bear a statement of substandard quality as follows:
 - (a) "Contains Excessive Bacteria" if the bottled water fails to meet the requirements of U.S. FDA 21 CFR Section 165.110(b)(2).
 - (b) "Excessively Turbid," "Abnormal Color," and/or "Abnormal Odor," as appropriate, if the bottled water fails to meet the requirements of U.S. FDA 21 CFR Section 165.110(b)(3).
 - (c) "Contains Excessive -----" with the blank filled in with the name of the chemical for which the Standard of Quality as described in U.S. FDA 21 CFR Section 165.110(b)(4) is exceeded.
 - (d) "Excessively Radioactive" if the bottled water fails to meet the requirements of U.S. FDA 21 CFR Section 165.110(b)(5).
2. Such labeling shall in no case be less than one-sixteenth of an inch.

E. U.S. FDA NUTRITIONAL REQUIREMENTS:

1. All nutrition labeling shall comply with the applicable provisions under U.S. FDA 21 CFR Section 101.9.
2. All claims of medicinal and/or health giving properties shall comply with the applicable provisions under U.S. FDA 21 CFR.
3. Such labeling shall in no case be less than one-sixteenth of an inch.

F. MAINE STATUTE REFERENCE. Product labeling must also comply with the provisions of State of Maine Title 32 M.R.S.A. Chapters 26, 26-A, 27 and 28.

9. INSPECTION

An annual sanitary survey of each water bottling plant shall be made by the Department to determine its conformance with the U.S. FDA requirements under 21 CFR Part 129, including the following standards:

A. PLANT SURROUNDINGS.

1. Immediate plant surroundings shall be kept clean, neat, and free from conditions which might attract or harbor flies, other insects, and rodents, or which otherwise constitute a nuisance or unsanitary conditions.
2. Surface drainage shall be diverted away from the source well.
3. Source well shall have a sanitary seal and the well house shall be secured with a lock.
4. Source overflow pipes and vents shall be screened with #24 mesh screening.

B. BUILDING AND ROOMS.

1. All rooms shall be of sufficient size to allow for the proper installation of equipment and to facilitate its maintenance.
2. All bottling rooms shall be separated from other plant operations or storage areas by tight walls and self-closing doors to protect against contamination. No storage should be permitted in bottling rooms.
3. Plant buildings shall be insect, bird and rodent proof.
4. Ambient ozone shall be vented to the outside, and the vent shall have a #24 mesh screen. All persons engaged in handling ozonator water disinfection components must be provided with proper Personal Protective Equipment (PPE), and shall use gloves and a chemical cartridge respirator. All such equipment shall be maintained in a clean and serviceable condition in accordance with Occupational Safety and Health Administration (OSHA) and Maine Department of Labor (DOL) standards.
5. Piping system shall be free of excessive leaks or other sources of contamination.
6. Locker and lunch rooms shall be separate from plant operations and storage areas, and have self-closing doors, shall be clean and sanitary, and have refuse containers provided.

C. FLOORS.

1. The floor shall be smooth, impervious, properly drained, and maintained in a state of good repair, and shall be kept clean and free from waste, litter, and extraneous material. Floors in new construction in wet areas shall be pitched one-fourth inch per foot to properly trapped drains.

2. Floors in the bottling room shall be cleaned and disinfected daily in accordance with Section 9(F)(3) of these Rules.
3. Wastewater shall be disposed of in accordance with State and Local Plumbing Codes.

D. WALLS AND CEILINGS.

1. Walls and ceilings of bottling areas shall have a smooth, cleanable surface and shall be kept clean and in good repair.

E. DOORS AND WINDOWS.

1. All outside openings into the bottling facility and bottling areas shall be effectively screened with #24 mesh screening and/or otherwise protected against the entry of insects, dust, and airborne contamination.

F. EQUIPMENT FOR COLLECTION, STORAGE AND PROCESSING OF WATER.

1. EQUIPMENT. All equipment shall be of a sanitary design and shall be constructed of non-toxic, non-absorbent material which will withstand sanitization and which will not impart flavors, color or odor to the bottled water.
2. STORAGE TANKS. Storage tanks shall be tightly closed to exclude all foreign matter. Storage tanks shall be thoroughly cleaned a minimum of once per year, in accordance with the manufacturer's specifications and in compliance with Section 9(F)(3) of these Rules.
3. CLEANING/SANITIZING PROCEDURE. All product storage tanks, piping, filling equipment, container washers, cappers and other equipment used to store, handle, transport, and package the water shall be inspected, maintained, cleaned, and sanitized according to the following requirements:
 - (a) Wash surfaces with 100 ppm chlorine water solution at 75° F or higher for not less than 1 minute followed by flushing with operations water or product water (to obtain 100 ppm, add 1.0 oz. of approved chlorine bleach (5.25% chlorine) to 4 gallons of water).
 - (b) Spray wet surface with 100 ppm chlorine solution at 75° F for not less than 1 minute followed by flushing with operations water or

product water. This is to be used on surfaces that are not reached by the above treatment.

- (c) Satisfactory results may also be obtained by use of other bactericides such as quaternary ammonium compounds, organic chlorine compounds, and bactericidal agents containing iodine or bromine. As the effectiveness of these agents may be expected to vary with temperature, pH, and with other components of specific formulations, they should not be used unless the Department has approved their usage under specified condition.
 - (d) An alternative cleaning and sanitizing procedure may be employed in accordance with the chemical manufacturer's recommendations and with prior approval from the Department.
 - (e) Wastewater shall be disposed of in accordance with State and Local Plumbing Codes.
- 4. **SANITIZING FILTERS.** Softeners, charcoal filters, de-mineralizers, etc., shall be sanitized on the basis of recommendations by the manufacturer. Such manuals shall be available for inspection by the Department.
- 5. **MULTIFOODS EQUIPMENT.** In order to minimize the potential for microbiological contamination of the finished product, noncarbonated bottled water shall not be transported, stored, processed, or bottled in or through lines or equipment through which milk, fruit juice, or other food products have passed and is likely to contribute nutrients for microbial growth, unless said lines, equipment, or holding tanks have been cleaned in accordance with Section 9(F)(3) of these Rules.
 - (a) Bottled water may be processed through lines or equipment used also for other food products under the following conditions:
 - 1. Before being used for the bottling of water - filling equipment, process lines, including storage tanks and associated equipment which is designed to be cleaned in-place and which is used for filling other food products shall be thoroughly cleansed and sanitized in-place in accordance with the manufacturer's specifications and in compliance with Section 9(F)(3) of these Rules.
 - 2. Immediately following completion of filling operations for any food product other than water, the filler shall be thoroughly rinsed internally and externally with potable water.

3. Any alternate cleaning, rinsing, or sanitizing operations or processes not described in this Section shall be consistent with FDA requirements and receive prior Department approval.
6. **DEDICATED EQUIPMENT.** Bottled water shall not be transported or stored in bulk tanks, or processed or bottled through equipment or lines used for any non-food product.

G. CLEANING AND SANITIZING CONTAINERS.

1. **MULTI-USE CONTAINERS.** All multi-use containers shall be thoroughly cleaned by washing with an effective, approved cleansing solution, having a temperature of not less than 120° F, followed by application of a bactericidal solution as described in the following sections.
 - (a) **Method A:** Clean by exposing all surfaces with not less than 2½ % approved caustic solution at a minimum temperature of 120° F for not less than 1 minute where high velocity jets are used and for not less than 3 minutes where soaker type container washers are used, followed by a thorough rinsing with operations water or product water.
 - (b) **Method B:** Sanitize with 100 ppm chlorine water solution at 75° F for not less than 30 seconds, followed by a thorough rinsing with operations water or product water.
 - (c) **Method C:** Sanitize with 200 ppm approved quaternary ammonium water solution at 75° F for not less than 2 minutes, followed by a thorough rinsing with operations water or product water.
 - (d) An alternative cleaning and sanitizing procedure may be employed in accordance with the tank manufacturer recommendations and with prior approval from the Department.
2. **QUALITY ASSURANCE/QUALITY CONTROL.** Containers shall be protected from contamination between washers and filters. Used containers shall not be stored in the area provided for the storage of sanitized containers. Containers shall be inspected by visual and olfactory means (at a minimum) to prevent the use of contaminated bottles.

H. FILLING AND CLOSING CONTAINERS:

1. **CONTAMINATION PREVENTION.** Filling and closing operations shall be conducted to prevent contamination of water being bottled.
2. **FILTER RESERVOIR.** The filter reservoir shall be kept covered at all times and the inlet designed to prevent entrance of condensation.
3. **FILLER.** Filling valves shall be equipped with a condensation-diverting apron to prevent any outside condensate from dripping into the container being filled.

I. CROSS CONNECTIONS:

1. **CROSS CONNECTIONS ARE PROHIBITED.** No cross-connections shall exist between the product water supply lines and any other sources of water. Where operations water from a municipal or other regulated source is supplied to washers and may be used for flushing, the use of separate lines, valves, and pumps shall be employed for each water source.

J. PERSONNEL-CLEANLINESS:

1. **HAND WASHING.** Hands shall be thoroughly washed before commencing plant functions, and as often as may be required to remove soil and contamination, and upon returning from the toilet room.
2. **CLOTHING.** All personnel shall wear clean outer garments, and wear hairnets, headbands, caps or other hair restraints.
3. **JEWELRY.** Employees shall remove all insecure jewelry to prevent contamination of product or equipment, excluding wedding bands.
4. **SICK EMPLOYEES.** No person infected with any disease in a communicable form, or while a carrier of such disease, and no person with an infected cut or lesion shall work in any processing area in any capacity where there is a likelihood of such person contaminating product-contact surfaces with pathogenic organisms.
5. **CONTAMINATION PREVENTION.** Employees shall take necessary precautions to protect against contamination of product, product-contact surfaces, or product-packaging materials with microorganisms or foreign substances including, but not limited to: perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.
6. **EDUCATION AND TRAINING.** Product handlers and supervisors shall receive appropriate training in proper principles, techniques and practices

of plant and production sanitation and shall be informed of the public health dangers of poor personal hygiene and unsanitary practices.

7. SUPERVISION. Responsibility for assuring compliance by all personnel with all requirements of Section 9 of these Rules shall be clearly assigned to competent supervisory personnel.

K. TOILET FACILITIES:

1. TOILETS. Toilets shall be adequate for the number of employees, and toilet rooms shall have self-closing doors not opening directly into any rooms used for manufacturing, processing or packaging. Toilets and all hand washing facilities shall be maintained in a clean and sanitary condition. The toilet room shall be ventilated to the outside, kept free of odors, and be in good repair. Washable receptacles shall be provided for disposal of hand drying articles or waste material. A covered waste receptacle must be provided in toilet rooms that are used by women.
2. WASTEWATER DISPOSAL. All plumbing shall comply with the State and Local plumbing codes.

L. HANDWASHING FACILITIES.

1. Hot and cold, running water, soap, and individual sanitary towels shall be provided.
2. Hand washing facilities shall be kept clean and shall be conveniently located to the bottling area and toilet facilities.
3. Employee hand wash reminder signs shall be posted at each hand washing facility.

M. STORAGE OF SINGLE SERVICE CONTAINERS.

1. Appropriate clean, dry storage facilities shall be provided for single service containers, closure materials, paper for wrapping, adhesives and other production materials to provide protection from splash, insects, dust, and other contamination.
2. The materials shall be stored on pallets 6 inches above the floor and 18 inches away from any wall to facilitate cleaning and further provide protection from contamination.
3. Partially used cartons of single service glass, plastic bottles, caps or other closures material shall be resealed between uses.

N. ANIMALS.

1. No animals or fowl shall be kept or allowed in any bottling works or other place where bottled waters are produced. Effective measures shall be taken to prohibit contamination, in or on the premises by animals or insects.

O. TEST KITS.

1. SANITIZING SOLUTIONS. Test kits shall be kept at the bottling plant for purposes of checking the strength of the various sanitizing solutions.
2. DISINFECTION. Test kit(s) shall be kept available at the bottling plant for purposes of checking ozone or chlorine-finished product residuals.

10. CONTAINERS.

- A. The Bottles and/or containers used to package water, under these regulations, shall be made of materials approved by the Department.
- B. Glass containers are generally approved for multiple use, but must be sanitized as specified in Section 9(F)(3) of these Rules.
- C. Plastic and paper products are approved for single-service containers.
- D. All containers and closures shall be sampled and inspected to ascertain that they are free from contamination. At least once each 3 months, a bacteriological swab and/or rinse count should be made from at least four containers and closures selected just prior to filling and sealing. No more than one of the four samples may exceed more than one bacteria per milliliter of capacity or one colony per square centimeter of surface area. All samples shall be free of coliform organisms. Tests shall be performed either by qualified plant personnel or a certified laboratory.

11. SEALING OF BOTTLES.

- A. Immediately after filling, bottles shall be sealed in a manner which will adequately protect the quality of the contents of the bottles and prevent contamination of the end of the bottlenecks.
- B. Corks are subject to bacterial contamination and are, therefore, not acceptable for use.

- C. If screw or snap caps are used, they shall be new caps or shall be subjected to a sanitizing treatment equivalent to that required for bottles, see Section 9(F)(3) of these Rules.
- D. Only new crown caps shall be used.
- E. New screw, snap and crown caps may be used without prior sanitizing, only if received in a condition of known cleanliness and freedom from bacterial contamination.
- F. It is recommended that single service caps having a tamper proof and/or destructible seal be used on all containers.

12. BULK WATER TRANSPORT

- A. **PROHIBITION.** Except as otherwise provided in this section, no person may transport water for commercial purposes by pipeline or other conduit or by tank truck or in a container, greater in size than 10 gallons, beyond the boundaries of the municipality or township in which water is naturally located or any bordering municipality or township. 22 MRSA § 2660 defines when a permit is necessary to transport water for human consumption across town lines within the State of Maine.
- B. **EXCEPTIONS.** The prohibition in this section does not apply to:
 - 1. Any water utility as defined in Title 35-A.
 - 2. Water transported for use in well drilling, construction activities, concrete mixing, swimming pool filling, servicing portable toilets, firefighting, hospital operations, aquaculture, agricultural applications or civil emergencies.
 - 3. Water distilled as a by-product of a manufacturing process.
 - 4. Water transported from a water source that, before July 1, 1987, was used to supply water for bottling and sale, and which is used exclusively for bottling and is sold in its pure form or as a carbonated or flavored beverage product.
- C. **PERMIT REQUIRED.** The Commissioner, after consultation with the Public Utilities Commission and the State Geologist, and upon the recommendations of the Department, may authorize transport of water for commercial purposes if the Commissioner finds that:

1. Transport of the water will not constitute a threat to public health, safety or welfare;
 2. The water is not available naturally in the location to which it will be transported; and
 3. Failure to authorize transport of the water would create a substantial hardship to the potential recipient of the water. Any authorization under this subsection must be for a period not to exceed 3 years, but may be renewed subject to the same criteria. [1997, c. 587, §2 (amd).]
- D. **EMERGENCIES.** In case of an emergency, any person may transport water as necessary for the duration of the emergency, but the person transporting the water must inform the Department within 3 days and the Department may determine when the emergency is over.
- E. **PENALTY.** Any person who transports water in violation of this section is guilty of illegal transport of water. Illegal transport of water is a Class D crime. Each shipment or day of transport, if by pipeline, is a separate offense.
- F. **SOURCE APPROVAL.** Bulk water sources shall meet the requirements of Sections 3 and 4 of these Rules, or be approved by the state agency having local jurisdiction. Bulk water shall be loaded, transported and unloaded in a sanitary manner to ensure the overall safety and quality of the finished water product.
- G. **MATERIAL.** Bulk water tankers, storage tanks, hoses, pumps and connections used for loading, transporting and unloading of bulk water shall be constructed of materials that are FDA food-grade, smooth, non-absorbent and easily cleanable such as stainless steel (300 series).
- H. **DEDICATED EQUIPMENT.** Tankers shall be dedicated for the hauling of bulk water only, for bottling purposes. Tankers that have been previously used to haul non-food commodities such as toxic materials, petroleum products, or other harmful substances shall not be used to haul drinking water for human consumption. Tankers shall be cleaned, sanitized and inspected internally for tank integrity on a routine basis.
- I. **CLEANING AND DISINFECTION PROCEDURES FOR MOBILE BULK STORAGE CONTAINERS (MBSC):**
1. Inspect the container to ensure that it is watertight and free of debris. Remove all debris.
 2. Disinfect the container for 30 minutes using not less than 100 ppm chlorine solution. Alternatively, “super ozonated” (greater than 1 ppm)

water may be used. Allow disinfected water to flow through all pipes and overflows. Use gloves and avoid breathing fumes (wear an OSHA approved chemical cartridge respirator if necessary). Take all necessary safety precautions in accordance with OSHA standards.

3. Mix solution throughout the container. Scrub the inside of the container with a clean long handled brush to remove bio-film and other accumulated debris.
 4. Fill tank completely full, with not less than 10 ppm chlorine solution. Allow at least 1-hour contact time.
 5. Drain and rinse container with operations water.
 6. Fill tank with product (potable) water. Ensure that the free chlorine residual in the container is at least 2 mg/l. If ozonation is utilized, the ozone residual in the container shall be at least 0.2 mg/l. Record this measurement at the time of loading and unloading.
 7. Secure and lock access hatches to the container to prevent unauthorized access and potential contamination.
 8. An alternative cleaning and disinfection procedure may be employed in accordance with the tank manufacturer recommendations and with prior approval from the Department.
- J. **HOSES AND CONNECTIONS.** Connections (hoses) and pumps used for the loading and unloading of bulk water shall be properly maintained and stored to prevent contamination. When not in use, pumps, hoses, connections and fittings shall be properly capped, securely stored and protected from possible contamination. Manhole cover gaskets and safety seals shall be maintained to prevent possible contamination.
- K. **BACTERIA SAMPLING.** Representative samples shall be taken from shipments of bulk water for the analyses of total coliform bacteria. The minimum frequency of sampling shall be one sample from each tanker on a weekly basis, or more frequently as determined by the Department.
- L. **RECORDS.** Shall be maintained for a minimum of two years, to include the following information:
1. Name of the transporter and/or driver.
 2. Tanker number.

3. Date of shipment.
 4. Vendor and location of the source water.
 5. Name of the receiver and the location to which the water was shipped.
 6. Date of delivery.
 7. Date of tanker cleaning and sanitization (includes name of operator).
 8. The concentration of the disinfectant residual (if required by the local state agency having jurisdiction) at the time of loading and unloading.
 9. Results of total coliform bacteria testing performed on representative samples taken from shipments of bulk water for each tanker to be performed at least once per week.
- M. TANK SHED. Stationary (or non-mobile) bulk water storage containers shall be housed in an enclosed structure with concrete slab (or equivalent) foundation. The structure shall have adequate floor drainage. Doors and windows shall have 24-mesh screens to prevent pests from entering.

13. RECORDS

- A. Records shall be maintained of all inspections and reports. Records of all water quality bacteriological and chemical testing shall be maintained for 5 years by the water supplier and the Department.
- B. Records shall be maintained of daily production operations and shall include the date, number of units packaged and number of units delivered. The names of people who obtain water should also be maintained.

14. APPROVAL REQUIRED

- A. FACILITIES. Plans and specifications for any major alternation of existing bottled or bulk water facilities or any new construction must be approved by the Department before any work is commenced.
- B. TREATMENT. Plans and specifications for any alteration of existing treatment processes or any new treatment process must be approved by the Department before installation is commenced. It is recommended that at least thirty (30) working days be allowed for plan review.

- C. CHANGE IN OWNERSHIP. A permit holder shall notify the Department within 5 days after any change in ownership, and at least 30 days prior to any change of the name or location of the plant and in all cases promptly submit to the Department written documentation reflecting such change(s).
- D. CHANGE/ADDITION OF A SOURCE. Prior to the time that a water source is changed or a new source is used in addition to the existing approved source(s), if the new source is not a public water supply, the permit holder shall obtain an inspection and approval of the new source by the governmental authority having jurisdiction, and shall submit a copy of such inspection and approval to the Department. The permit holder shall also submit to the Department information in accordance with Sections 3 and 4 of these Rules, prior to the sale of products using the new source. If the new source is a public water supply, the permit holder shall notify the Department of the change or addition of source.

15. VARIANCES AND EXEMPTIONS

- A. The Department may issue variances and exemptions as provided for in 22 M.R.S.A. § 2613. Applications may be obtained by contacting the.

16. ORDERS, EMERGENCY POWERS, PENALTIES

- A. Pursuant to 22 M.R.S.A. § 2614, the Department is authorized to issue orders to any person to comply with the requirements of these regulations, and is further authorized to petition to compel compliance with such orders.
- B. Pursuant to 22 M.R.S.A. § 2614, on receipt of information that due to the actual or threatened use of contaminants to a bottled water system, or for other reasons, there is an imminent and substantial endangerment to the health of persons, the Department may take such actions, including, but not limited to, issuing emergency orders or commencing court action, as deemed necessary to protect the public health.
- C. Pursuant to 22 M.R.S.A. § 2617 and § 2620, any person willfully violating any portion of these regulations, may be subject to a fine. Each day of operation in violation shall constitute a separate offense. In addition, as indicated in subparagraph 2 of 22 M.R.S.A. § 2617, injunctive relief may be obtained to prevent the violation of any rule, in accordance with State law.

17. PROHIBITED ACT

- A. **PROHIBITED ACTS.** It is prohibited by any water system to buy back or accept already sold product water from a consumer.
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STATUTORY AUTHORITY: 22 M.R.S.A. §§42 and 2601 *et seq.*

EFFECTIVE DATE:

December 7, 1979

AMENDED:

November 1, 1983 (filed with Secretary of State November 17, 1983)

EFFECTIVE DATE (ELECTRONIC CONVERSION):

May 5, 1996

AMENDED:

May 7, 2001